Pending Claims – Tejidor et al.
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1. (Twice Amended). A reagent for an assay to determine a hemostatic potential of a blood or plasma sample, said reagent comprising a coagulation activator wherein said activator is present at a concentration level [within a range sufficient] to trigger a thrombin formation but [insufficient] not to result in a complete fibrin polymerization of said blood or plasma sample, wherein said reagent [may be] is utilized to assess a hypocoagulable, normal [or] and hypercoagulable condition in a single assay.

2. (Original) The reagent of claim 1, further comprising vesicles or liposomes.

3. (Original) The reagent of claim 1, wherein the coagulation activator comprises tissue factor.

4. (Original) The reagent of claim 3, further comprising a metal cation or metal salt which dissociates into a metal carton.

5. (Previously Amended). The reagent of claim 1, wherein the reagent indicates a sample to be any of hypocoagulable, normal or hypercoagulable, depending upon the condition of the patient from which the sample was taken.

6. (Previously Amended). The reagent of claim 1, wherein the reagent indicates a patient, from which the sample was taken, to have any of thrombotic tendency, hemorraghic tendency, or stasis, depending on the patient.

7. (Original) The reagent of claim 2, wherein the vesicles comprise phospholipids.

8. (Original) The reagent of claim 7, wherein the phospholipids comprise one or more of phosphatidylcholine, phosphatidylethanolamine and phosphotidylserine.

9. (Twice Amended). The reagent of claim 8, wherein the phospholipids comprise a phospholipid mixture comprising [all of] phosphatidylcholine, phosphotidylethanolamine, and phosphatidylserine and at a ratio of approximately from 1 to 10 [mole] percent phosphotidylserine and from about 5 to 30 [mole] percent phosphatidylethanolamine and the remainder phosphatidylcholine.

10. (Original) The reagent of claim 9 wherein the phospholipid mixture comprises approximately 70 ~~mole~~ percent phosphatidylcholine, 20 ~~mole~~ percent phosphatidylethanolamine and 10 ~~mole~~ percent phosphotidylserine.

11. (Original) The reagent of claim 3, wherein the tissue factor comprises recombinant or purified tissue factor, truncated tissue factor, or cells expressing tissue factor on their surface.

12. (Twice Amended). The reagent of claim 4 wherein the metal cation is selected from the group consisting of magnesium, calcium [or] and manganese.

13. (Original) The reagent of claim 4, wherein the metal salt is a halide of magnesium, calcium or manganese.

14. (Original) The reagent of claim 1, further comprising an activator of an anticoagulant pathway.

15. (Original) The reagent of claim 14, wherein the activator of the anticoagulant pathway is an activator of protein C.

16. (Twice Amended). The reagent of claim 15 wherein the protein C activator is purified human thrombomodulin, purified non-human mammalian thrombomodulin, soluble ~~thrombomodulin~~ [or] membrane associated thrombomodulin, native thrombomodulin [or] thrombomodulin reconstituted with phospholipids, partially [or fully] glycolsylated thrombomodulin, fully glycolsylated thrombomodulin, or fully deglycosylated thrombomodulin.

17. (Previously Amended). The reagent of claim 1, further comprising at least one member of the group consisting of buffers and stabilizers.

18. (Original) The reagent of claim 11, wherein the tissue factor is at a concentration of 11 picomolars or less.

19. (Original) The reagent of claim 18, wherein the tissue factor is at a concentration of 6 picomolars or less.

20. (Original) The reagent of claim 19, wherein the tissue factor is at a concentration of 3 picomolars or less.

21. (Original) The reagent of claim 1, further comprising phospholipids at a concentration of from 10 to 300 micromolar.

22. (Original) The reagent of claim 21, wherein the phospholipids are at a concentration of from 50 to 200 micromolar.

23. (Original) The reagent of claim 15, wherein the protein C activator is thromobomodulin at a concentration of 30 nanomolar or less.

24. (Original) The reagent of claim 23, wherein the thrombomodulin is at a concentration of from 5 to 20 nanomolar.

25. (Original) The reagent of claim 13, wherein the metal salt is at a concentration of from 5 to 50 mM.

26. (Original) The reagent of claim 25, wherein the metal salt is at a concentration of from 15 to 35 mM.

27. (Twice Amended). A reagent comprising:

a coagulation activator at a concentration of 11 picomoles or less, wherein said reagent [may be] is utilized to assess a hypocoagulable, normal [or] and hypercoagulable condition in a single assay.

28. (Previously Amended). The reagent of claim 27, further comprising vesicles or liposomes.

29. (Original) The reagent of claim 27, wherein the coagulation activator comprises tissue factor at a concentration of 11 picomolar or less.

30. (Original) The reagent of claim 29, further comprising a metal cation or metal salt which dissociates into a metal cation.

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31. (Previously Amended). The reagent of claim 27, wherein the reagent indicates a sample to be any of hypocoagulable, normal or hypercoagulable, depending upon the condition of the patient from which the sample was taken.

32. (Previously Amended). The reagent of claim 27, wherein the reagent [is capable of indicating] indicates a patient, from which the sample was taken, to have any of thrombotic tendency, hemmoraghic tendency, or stasis, depending on the patient.

33. (Original) The reagent of claim 28, wherein the vesicles comprise phospholipids.

34. (Original) The reagent of claim 33, wherein the phospholipids comprise one or more of phosphatidylcholine, phosphatidylethanolamine and phosphotidylserine.

35. (Previously Amended). The reagent of claim 34, wherein the phospholipids comprise all of phosphatidylcholine, phosphatidylethanolamine and phosphatidylserine and at a ratio of approximately from 0 to 10 ~~mole~~ percent phosphatidylserine and from about 5 to 30 ~~mole~~ percent phosphatidylethanolamine and the remainder phosphatidylcholine.

36. (Original) The reagent of claim 29, wherein the tissue factor comprises recombinant or purified tissue factor, truncated tissue factor, or cells expressing tissue factor on their surface.

37. (Twice Amended). The reagent of claim 30, wherein the metal cation is a divalent metal cation selected from the group consisting of manganese, calcium [or] and manganese.

38. (Original) The reagent of claim 30, wherein the metal salt is a halide of magnesium, calcium or manganese.

39. (Original) The reagent of claim 27, further comprising an activator of an anticoagulant pathway.

40. (Original) The reagent of claim 39, wherein the activator of the anticoagulant pathway is an activator of protein C.

41. (Original) The reagent of claim 40, wherein the protein C activator is purified human thrombomodulin, purified non-human mammalian thrombomodulin, soluble or membrane associated thrombomodulin, native thrombomodulin or thrombomodulin reconstituted with phospholipids, partially or fully glycolsylated thrombomodulin, or fully deglycosylated thrombomodulin.

42. (Previously Amended). The reagent of claim 27, further comprising at least one member selected from the group consisting of buffers and stabilizers.

43. (Original) The reagent of claim 36, wherein the tissue factor is at a concentration of 8 picomolars or less.

44. (Original) The reagent of claim 43, wherein the tissue factor is at a concentration of 6 picomolars or less.

45. (Original) The reagent of claim 44, wherein the tissue factor is at a concentration of 3 picomolars or less.

46. (Original) The reagent of claim 27, further comprising phospholipids at a concentration of from 10 to 300 micromolar.

47. (Original) The reagent of claim 46, wherein the phospholipids are at a concentration of from 50 to 200 micromolar.

48. (Original) The reagent of claim 40, wherein the protein C activator is thromobomodulin at a concentration of 30 nanomolars or less.

49. (Original) The reagent of claim 48, wherein the thrombomodulin is at a concentration of from 5 to 15 nanomolar.

50. (Original) The reagent of claim 38, wherein the metal salt is at a concentration of from 5 to 50 mM.

51. (Original) The reagent of claim 50, wherein the metal salt is at a concentration of from 15 to 35 mM.

52 ~~83~~. (Twice amended) The reagent of claim 16, [wherein the thrombomoduln comprises] further comprising heparin.

53 ~~84~~. (Original) The reagent of claim 16, wherein the thrombomodulin is relipidated with phospholipids comprising at least 10% phosphatidylethanolamine.

54 ~~85~~. (Original) The reagent of claim 2, wherein the vesicles comprise platelets, cellular debris, phospholipid vesicles or platelet microparticles.

55 ~~86~~. (Original) The reagent of claim 2, wherein the vesicles are phospholipid vesicles prepared by dilution, sonication, dialysis or extrusion.

56 ~~87~~. (Original) The reagent of claim 1, wherein the coagulation activator comprises tissue factor-rich mammalian tissue extracts, tissue factor purified from mammalian tissues or thromboplastin.

57 ~~88~~. (Twice Amended). The reagent of claim 1, wherein [said fibrin polymerization is preceded by an initiation phase, and wherein] the coagulation activator detects defects in an [the] initiation phase.

58 ~~89~~. (Previously Amended). The reagent of claim 41, wherein the thrombomodulin comprises heparin.

59 ~~90~~. (Original) The reagent of claim 41, wherein the thrombomodulin is relipidated with phospholipids comprising at least 10% phosphatidylethanolamine.

60 ~~91~~. (Original) The reagent of claim 28, wherein the vesicles comprise platelets, cellular debris, phospholipid vesicles or platelet microparticles.

61 ~~92~~. (Original) The reagent of claim 28, wherein the vesicles are phospholipid vesicles prepared by dilution, sonication, dialysis or extrusion.

62 ~~93~~. (Original) The reagent of claim 27, wherein the coagulation activator comprises tissue factor-rich mammalian tissue extracts, tissue factor purified from mammalian tissues or thromboplastin.

63 ~~94~~. (Twice Amended). The reagent of claim 27, wherein said coagulation activator is present at a concentration level [within a range sufficient] to trigger a fibrin polymerization, wherein [said fibrin polymerization is preceded by an initiation phase, and wherein] the coagulation activator detects defects in the initiation phase.